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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,150	06/08/2005	Sharon Katrina Watson	05-470	1497

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EXAMINER

LEE, JOHN W

ART UNIT	PAPER NUMBER
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2624

MAIL DATE	DELIVERY MODE
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11/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/538,150		WATSON ET AL.	
	Examiner		Art Unit	
	John Wahnkyo Lee		2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 19,21,23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18,20,22 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20051027</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 20051027, is attached to the instant Office action.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract has 150 words. It is required for the applicant to shorten the length of the abstract within the range of 50 to 150 words.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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4. Claim 25 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 25 is drawn to functional descriptive material NOT claimed as residing on a computer readable medium. MPEP 2106.IV.B.1(a) (Functional Descriptive Material) states:

“Data structures not claimed as embodied in a computer-readable medium are descriptive material per se and are not statutory because they are not capable of causing functional change in the computer.”

“Such claimed data structures do not define any structural or functional interrelationships between the data structure and other claimed aspects of the invention which permit the data structure's functionality to be realized.”

Claim 25, while defining a computer program, does not define a “computer-readable medium” and is thus non-statutory for that reasons. A computer program can range from paper on which the program is written, to a program simply contemplated and memorized by a person. The examiner suggests amending the claim to embody the program on “computer-readable medium” in order to make the claim statutory.

“In contrast, a claimed computer-readable medium encoded with the data structure defines structural and functional interrelationships between the data structure and the computer software and hardware components which permit the data structure's functionality to be realized, and is thus statutory.” - MPEP 2106.IV.B.1(a)

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 4 recites the limitation "locations." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 6-9, 11, 14, 17-18, 20, 22, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Madachy et al. ("Image Analysis For Automatic classification of mitotic cervical cells").

Regarding claim 1, Madachy teaches a method for the automated analysis of a digital image (abstract, "digital image analysis"; INTRODUCTION, page 372) comprising an array of pixels (TEXTURE, pages 373, "pixel") including the steps of: (a) identifying (abstract, "identifying mitotic ...") the locations of objects within the image which have specified intensity (abstract, "optical density") and size (abstract, "geometrical measures") characteristics; (b) defining regions of specified extent within the image which contain respective said objects (SHAPE, pages 373, lines 28-58); (c) deriving from the data within respective said regions one or more respective closed contours comprising points of equal intensities (TEXTURE, pages 373, "subregions based on density ... black and white pixels..."); and (d) estimating the curvature of at least one respective said contour within respective said regions at least to produce a measure of any concavity thereof (SHAPE, pages 373, "R(i)" and "curvature").

Regarding claim 6, Madachy discloses following step (a): selecting an intensity threshold (TEXTURE, pages 373, "15%") related to the mean intensity of pixels (TEXTURE, pages 373, "mean value") within the image in neighbourhoods of said locations (TEXTURE, page 373); creating a binary image according to whether pixels in the first-mentioned image (Figure 2; TEXTURE, pages 373) are above or below said threshold (TEXTURE, pages 373, "15%"); identifying regions in the binary image composed of connected pixels which are below said threshold in the first-mentioned image (Figure 2; TEXTURE, page 373, "white pixels"); and rejecting from further analysis those objects which correspond to such regions in the binary image which fall below a specified size or thickness (TEXTURE, page 373, "larger than ..").

Regarding claim 7, Madachy teaches wherein step (c) comprises, for respective said regions (TEXTURE, page 373, "subregions") deriving respective first (Figure 2; TEXTURE, page 373, "white pixel region") and second said contours (TEXTURE, page 373, "black pixel region") having respectively lower (TEXTURE, page 373, "optical density being 15% lower than mean value") and higher resolutions (TEXTURE, page 373, "optical density being 15% greater than mean value"), determining whether the sizes and locations of said first and second contours are consistent within specified criteria and, if so consistent, selecting said second contour for step (d) (TEXTURE, page 373, "the black and white regions are ... regions larger than 2 ... operation.").

Regarding claim 8, Madachy teaches the first said contour is derived by: seeking within the region one or more contours of respective specified intensities (Figure 2; TEXTURE, page 373, "white pixel region" and "black pixel region"); determining whether the or each

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such contour is a closed contour and meets specified location, size and/or intensity orientation criteria (METHOD, "continuous contours ... fixed size"; TEXTURE, page 373, "the black and white regions are ... regions larger than 2 ... operation."); and if more than one such contour is a closed contour and meets such criteria, selecting from the same the contour of the lowest intensity (Figure 2; TEXTURE, page 373, "white pixel region").

Regarding claim 9, Madachy teaches wherein said specified intensities (Figure 2; TEXTURE, page 373, "white pixel region") are no greater than that which corresponds to the contour of highest edge strength within the respective region (TEXTURE, page 373, "black pixel region").

Regarding claim 11, Madachy discloses the second said contour is derived by: seeking within the region a plurality of contours of respective specified intensities ranging between the lowest and highest intensities within the region (Figure 2; TEXTURE, page 373, "white pixel region" and "black pixel region"); determining whether each such contour is a closed contour and meets specified location, size and/or intensity orientation criteria (METHOD, "continuous contours ... fixed size"; TEXTURE, page 373, "the black and white regions are ... regions larger than 2 ... operation."); and if more than one such contour is a closed contour and meets such criteria, selecting from the same the contour having the highest edge strength (Figure 2; TEXTURE, page 373, "white pixel region").

Regarding claim 14, Madachy discloses further comprising the step of: (e) classifying objects into one of at least two classes (CELL CLASSIFICATION, page 373, "parameters") in accordance with a function of said measure of concavity of a contour (SHAPE, page 373, "R(i)") corresponding to the respective object and a measure of the mean intensity (TEXTURE, page 373, "mean value") of the respective object.

Regarding claim 17, Madachy discloses further comprising the step of: (f) counting the number of objects classified into a specified one of said classes (PREVIOUS EFFORTS, page 372, "counted mitoses in breast cancer ...").

Regarding claim 18, Madachy discloses wherein the image is of a histological or cytology specimen or of a soil sample (INTRODUCTION, page 372, "pre-scored specimens").

Regarding claim 20, Madachy discloses the image being of a section of breast tissue and said specified class is identified as the class of mitotic epithelial cell nuclei (PREVIOUS EFFORT, page 372, "counted mitoses in breast cancer ...").

Regarding claim 22, Madachy discloses a method for the automated identification of mitotic activity from a digital image (abstract, "digital image analysis" and "mitotic cells"; INTRODUCTION, page 372) of a histological specimen (INTRODUCTION, page 372, "pre-scored specimens"), including the steps of: (a) identifying (abstract, "identifying mitotic ...") the locations of objects within the image which have specified intensity (abstract, "optical density") and size (abstract, "geometrical measures") characteristics associated with epithelial cell nuclei (pages 372-374); (b) defining regions of specified extent within the image which contain

respective said objects (SHAPE, pages 373, lines 28-58); (c) deriving from the data within respective said regions one or more respective closed contours comprising points of equal intensities (TEXTURE, pages 373, "subregions based on density ... black and white pixels..."); and (d) estimating the curvature of at least one respective said contour within respective said regions at least to produce a measure of any concavity thereof (SHAPE, pages 373, "R(i)" and "curvature"). (e) classifying objects as representing mitotic cell nuclei as a function of at least said measure of concavity of a contour corresponding to the respective object (TABLES 1 and 2; page 374, "parameter statistics" and "classification").

Regarding claim 25, Madachy discloses a computer program comprising instructions to cause a computer to execute a method according to claim 1 (METHOD, page 373, "Gould/Denaza IP8500 image processor on a VAX host").

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 2-5, 10, and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madachy et al. ("Image Analysis For Automatic classification of mitotic cervical cells") in view of Netsch et al. ("Scale-Space Signatures for the Detection Clustered Microcalcifications in Digital Mammograms").

Regarding claim 2, Madachy teaches all the previous claim limitation except the one specified in claim 2. However, Netsch teaches wherein step (a) comprising the application of a radially-symmetric difference filter with zero mean (Fig. 3; equations (1)-(4); section III. A. Motivation and Outline, page 776, "circularly-symmetric Gaussian function").

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use Netch's method in Madachy's method to provide automated detection of microcalcifications as suggested by Netch (abstract).

Regarding claim 3, Netch further teaches the image is filtered at a plurality of resolutions of increasing scale (Figure 4; section III. A Motivation and Outline; pages 776-777, "scales $h=1, \dots$ ").

Regarding claim 4, Netch further teaches locations are identified in accordance with the locations of respective local extrema (abstract, "local maxima") in the output of said filter (abstract, "possible locations of ... local maxima ... filtered image ...").

Regarding claim 5, Netch further teaches including the step of sorting, in order of intensity (section III A. Motivations and Outline, "range of scales"), local extrema (section III A. Motivations and Outline, "local maxima") in the output of said filter (abstract, "possible locations of ... local maxima ... filtered image ...") and selecting for further analysis only those objects which correspond to a specified proportion of said extrema in such order (section III A. Motivations and Outline, "Detection ... filter ... threshold").

Regarding claim 10, Netch further teaches wherein step (a) comprising the application of a radially-symmetric difference filter with zero mean (Fig. 3; equations (1)-(4); section III. A. Motivation and Outline, page 776, "circularly-symmetric Gaussian function") and said first contour is derived by seeking one or more contours in the output of said filter for the respective region and said specified intensities are no greater than the zero level in such output (Figs. 3-5; equations (1)-(6); section III. A. Motivation and Outline, page 776, "circularly-symmetric Gaussian function").

Regarding claim 12, Netch further teaches step (d) including the application of a Probability Density Association Filter to respective said contours (Fig. 3; equations (1)-(4); section III. A. Motivation and Outline, page 776, "circularly-symmetric Gaussian function" and "Gaussian function is a type of a probability density function").

Regarding claim 13, Netch further teaches step (d) comprising, for respective said contours (III D. Feature Estimation by Signatures; pages 778, "cylinder"): measuring the curvature of the contour at a plurality of points around the contour, convexity and concavity being of opposite sign (equation (7); III D. Feature Estimation by Signatures; pages 778, "cylinder"); setting convex values of such curvature to zero (equation (7); III D. Feature Estimation by Signatures; pages 778, "cylinder"); plotting resultant values of curvature at said points against a measure of the distance of the respective point along the contour (Figs. 7-10); and computing as said measure of concavity the line integral of such plot (equations (7)-(16)).

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11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Madachy et al. ("Image Analysis For Automatic classification of mitotic cervical cells") in view of Soni et al. (US 5,363,850).

Regarding claim 2, Madachy teaches all the previous claim limitation except the one specified in claim 2. However, Soni discloses using a Fisher classifier (claims 5 and 6, "Fisher classification").

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use Soni's invention in Madachy's method to provide high resolution as suggested by Soni (col. 1, lines 8-10).

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Madachy et al. ("Image Analysis For Automatic classification of mitotic cervical cells") in view of DeLong (US 2002/0012466).

Regarding claim 2, Madachy teaches all the previous claim limitation except the one specified in claim 2. However, DeLong discloses the intensities of respective objects are normalised prior to step (e) (Fig. 2; claim 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use DeLong's invention in Madachy's method to provide an image analysis process which can cyclically and interactively approximate the wished and ideas of a user without the user having to have detailed knowledge of the image processing itself (paragraph [0006]).

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Wahnkyo Lee whose telephone number is (571) 272-9554. The examiner can normally be reached on Monday - Friday (Alt.) 7:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jingge Wu can be reached on (571) 272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

John W. Lee
(AU 2624)


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SUPERVISORY PATENT EXAMINER